

REMARKS/ARGUMENTS

Claims 1, 4-8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43 and 46-48 are pending in the present case and are currently under examination. No further amendments have been made to the claims. Reconsideration is respectfully requested in view of the remarks provided below

Applicants acknowledge, with appreciation, the Examiner's withdrawal of the objections to the claims as well as the withdrawal of the rejections under 35 U.S.C. § 112, first and second paragraphs. As such, there is only a single rejection remaining: claims 1, 4, 5, 6, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43 and 46-48 remain rejected under 35 U.S.C. § 103 as allegedly obvious. For the reasons set forth herein, this remaining rejection is overcome.

Rejection Under 35 U.S.C. § 103

Claims 1, 4, 5, 6, 7, 8, 11, 15-18, 21, 22, 24-26, 29-31, 35, 38, 39, 41-43 and 46-48 remain rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 6,110,676 (Coull *et al.*) in view of U.S. Patent No. 5,612,458 (Hyldig-Nielsen *et al.*) and U.S. Patent No. 5,225,584 (Brooks *et al.*). In support of this rejection, the Office Action states: “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Coull *et al.*, which includes the use of antibodies that bind to the PNA-DNA or PNA:RNA complex, by use of a solid support such as those identified by Brooks and known in the art as disclosed by applicant, as such would have accorded the ordinary artisan with an efficient, sensitive, and reproducible method of detection.” (see, page 4 of the Office Action). For the reasons set forth below, Applicants respectfully traverse this rejection.

As a preliminary point, the present invention relates to a particular method of distinguishing a microbial organism of interest from a cross-reacting organism in a sample.

Claim 1 requires a method wherein a sample is treated with:

- a detectable molecular probe; **and**
- a solid carrier with an immobilized binding partner.

As set out in the claims, one of these species is reactive with the microbial organism of interest only and not the cross-reacting organism, and the other of these species may be reactive with both the microbial organism of interest and the cross-reacting organism. Thus, after **both** treatments, the microbial organism of interest can be distinguished.

It is respectfully pointed out that the Examiner has not identified any teaching in the prior art of a method of this type. Instead, the Examiner has simply indicated that various elements used in the method claimed, such as PNA, antibodies, chemiluminescent or fluorescent labels, exist in the art, but the Examiner has never identified in the prior art where the particular method claimed is taught or suggested. For instance, the Examiner has indicated: that Coull *et al.* disclose methods of determining the presence of a nucleic acid in a sample; that Coull *et al.* disclose that the hybridization reaction comprises the use of PNA probes that are detectable yet unlabeled; that Hyldig-Nielsen *et al.* disclose the development and use of antibodies that bind specifically to PNA:DNA as well as PNA:RNA duplex structures and how these antibodies can be used to detect the presence of target nucleic acids; that Hyldig-Nielsen *et al.* disclose that the antibodies may be attached to a variety of detectable materials (such as chemiluminescent or fluorescent); and that Brooks *et al.* disclose the development and use of various chemiluminescent labels, and that these labels can be used in combination with immunoassays as well as nucleic acid hybridization assays.

However, such disclosures in the prior art are not tantamount to teaching a method wherein a sample is treated with: a detectable molecular probe; and a solid carrier with an immobilized binding partner, wherein one of these species is reactive with the microbial organism of interest only and not the cross-reacting organism, and the other of these species may be reactive with both the microbial organism of interest and the cross-reacting organism, and wherein after **both** treatments, the microbial organism of interest can be determined.

If the Examiner wishes to maintain an obviousness rejection and takes the view that the prior art discloses a method of the type required by claim 1, Applicants would be grateful if he would set out in detail where the combination of features and steps can be found in the prior art. Applicants simply cannot find the combination of features or the combination of steps in the prior art.

The advantages of a method of the type presently claimed are set out in the specification at page 24, lines 16-25:

It should be noted that certainty at two levels of molecular discrimination is very useful since although binding partners and molecular probes are designed to be selective, they cannot be tested for cross-reaction against all organisms or other interfering matter. Hence, even if some level of cross-reactivity occurs in the assay with either of the molecular probe or binding partner, because the selectivity substantially differs at each different level of molecular discrimination, it is not likely that a particular cross reacting species will exhibit cross reactivity at both levels of discrimination. Consequently, the certainty of a result is significantly increased where a positive result requires, as does certain embodiments of this invention, that the assay performs an interrogation at two levels of molecular discrimination.”

Thus, Applicants submit that, in the absence of any indication that the prior art provides such a method (an not just the elements used in carrying out the method), such a method **must be** considered non-obvious and, thus, patentable. The prior art **fails** to provide the requisite indication. Accordingly, Applicants urge the Examiner to withdraw the remaining rejection under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

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